IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

The Ansar Group, Inc.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	**Civil Action No. 4:12-0386**
	§	
Medeia, Inc.	§	
	§	
	§	
Defendant.	§	

ORDER

This patent infringement suit is before the Court for construction of the disputed terms in United States Patent No. 7,079,888 (the "'888 Patent") and United States Patent No. 7,529,579 (the "'579 Patent"). On July 16, 2013, the Court conducted a hearing pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (the "*Markman* hearing"). During the *Markman* hearing, the parties presented arguments in support of their proposed constructions of the disputed terms. Having heard those arguments and having examined the claim language, patent specification, and the prosecution history, the Court issues this Memorandum construing the disputed claim terms as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

I.

A.

This suit involves Plaintiff's two patents, United States Patent No. 7,079,888 (the "'888 Patent"), entitled "Method and Apparatus for Monitoring the Autonomic Nervous System Using Non-stationary

Spectral Analysis of Heart Rate and Respiratory Activity" and United States Patent No. 7,529,579 (the "'579 Patent"), entitled "Methods for Real-Time Autonomic Nervous System Monitoring Using Total Heart Rate Variability, and Notched Windowing."

In general, the patents-in-suit relate to systems for monitoring the autonomic nervous system, and more specifically to a system for using real-time heart rate spectral analysis to monitor the autonomic nervous system.

The involuntary actions of the body, such as breathing, blood pressure, and heart rate are controlled by what is called the autonomic nervous system (also referred to as "ANS"). The ANS has two major components: The first is the sympathetic nervous system, which causes the heart rate and breathing to speed up, usually in response to some kind of stress. The sympathetic nervous system is commonly discussed in terms of the body's fight-or-flight reaction, but it is always active at some basic level. The second component of the ANS is the parasympathetic system. It works as a somewhat inverse mechanism to the sympathetic system to control the body's maintenance functions, such as digestion. In a healthy person, these systems are balanced, but they can be thrown out of balance when a person is sick. If that unbalance continues, it can impair important functions of the body. It turns out that the balance between these two systems can be assessed by a detailed analysis of a patient's heart rate and respiration. The patents-in-suit relate to methods and systems for monitoring the ANS by analyzing the variations in heart rate and respiratory activity.

An effective method to monitor the ANS is to monitor the function of the heart and the lungs, using the heart as "a window" to study the ANS. '888 Patent at 2:18-23. The most commonly known measure of heart rate is the pulse, measured in beats per minute, typically observed at the wrist or neck. The '579 Patent at 2:16-30. Each pair of adjacent beats also has a period, or time between the starting

points for each beat. It is known in the art, however, that heartbeats are not uniform. Some are closer together, others farther apart, which changes the pulse and period from beat to beat, a phenomenon called heart rate variability. It is through this variability that the sympathetic and parasympathetic ANS may be assessed.

One method for collecting heart rate variability data is illustrated in Figure 1, which is a schematic of an electrocardiogram (commonly referred to as an "ECG" or "EKG") signal for three heartbeats. Id. at ¶¶ 18-20. Heart periods are typically determined by measuring the time between the peaks of two adjacent beats, labeled as "R", which results in a periodic interval known as the "R-R interval". The '888 Patent at 4:62 to 5:26. In Figure 1, the R-R interval for the second pair of beats (R-R int.2) is illustrated as a longer heart period than the heart period for the first pair of beats (R-R int.1).

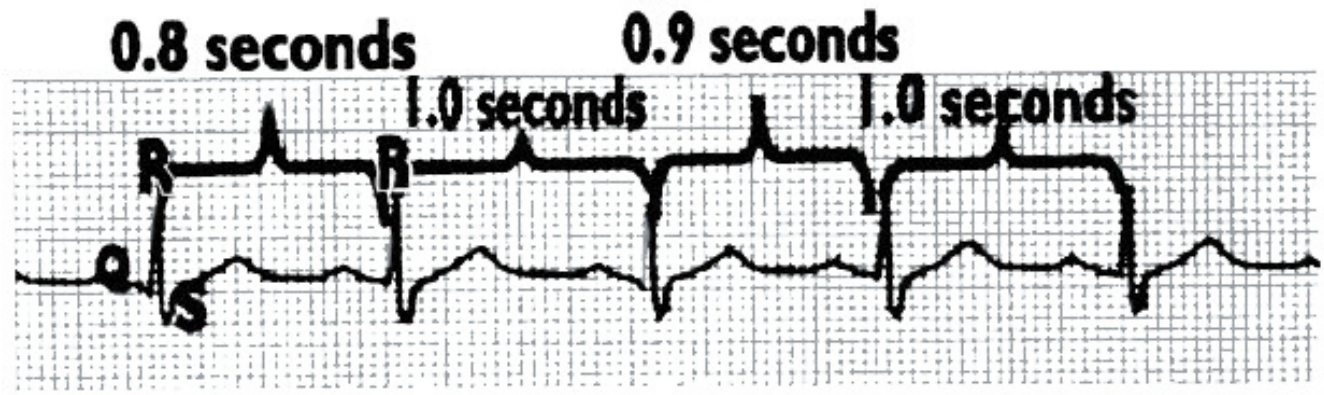

Figure 1. EKG Signal illustrating the heart period between pairs of consecutive beats.

In Figure 1, the heart period for the first pair of consecutive beats is 0.8 seconds, the heart period for the second pair of consecutive beats 1.0 seconds, 0.9 seconds for the third pair and 1.0 seconds for the fourth pair. In addition to the heart period the patents-in-suit refer to heart rate variability data in the form of "instantaneous heart rate," defined in the '888 Patent's specification as 60/heart period. The '888 Patent at 6:15. Thus, from Figure 1, above, the instantaneous heart rate, in beats per minute, for the

first pair of consecutive beats is 60/0.8, or 75 beats per minute. The instantaneous heart rate for the second pair of beats in Fig. 1 is 60/1, or 60 beats per minute.

The heart rate variability data is prepared for frequency analysis by plotting that data into a waveform. An example waveform of instantaneous heart rates is shown in Fig. 2. Frequency analysis is conducted on waveforms such as this to extract information about sympathetic ANS and parasympathetic ANS activities.

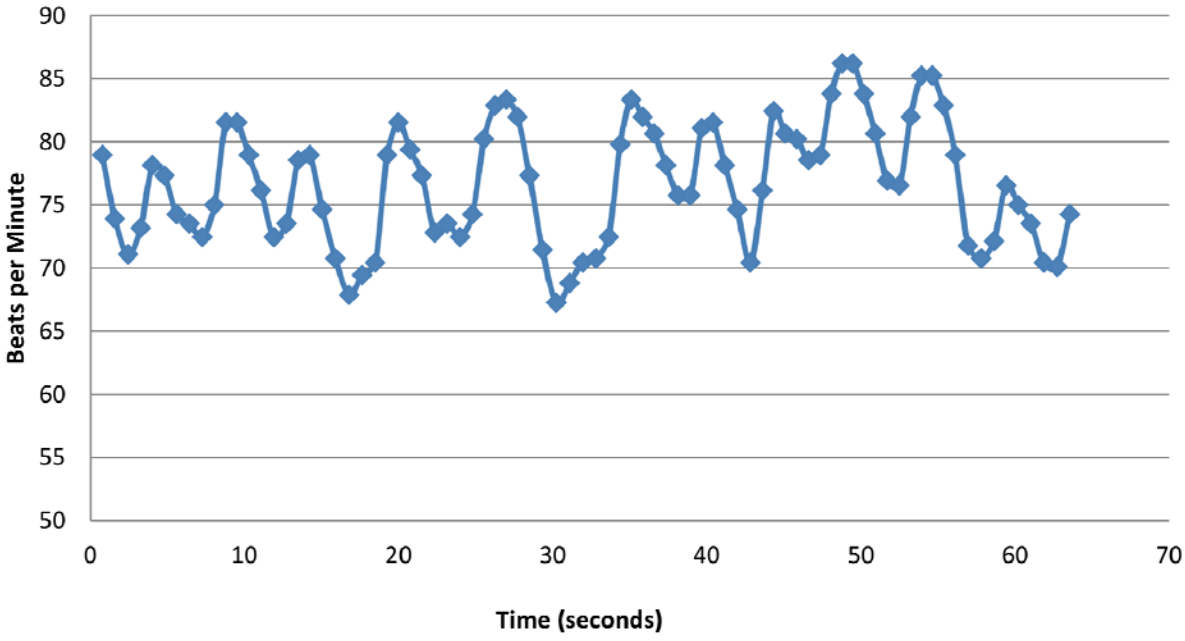

Fig. 2—Example waveform of instantaneous heart rates over time. As discussed below, this wave form is non-stationary as suggested by the very irregular peaks and valleys in the line.

As the heart rate variability data is measured and plotted (either as heart period or as instantaneous heart rate), data from selected time intervals is analyzed using various techniques. See e.g., the '888 Patent at 5:26-28. (a sequence of R-R intervals becomes an RR-interval tachogram); 5:29-6:11 (correcting "disturbed" R-R intervals); 6:17-19 (processing of corrected R-R interval data). These

techniques extract information that reflect the activities of "speeding up" (sympathetic) and "slowing down" (parasympathetic) that led to the observed heart rate variations. Id. at 9:9– 10:9. Such techniques, including the previously known fast Fourier transform technique (the '888 Patent at 2:53-56), continuous wavelet transform process described in the '888 Patent, and the short-time Fourier transform process described in the '579 patent, may be used to generate a power spectrum, such as is shown in Figure 3. '888 Patent 8:61-64.

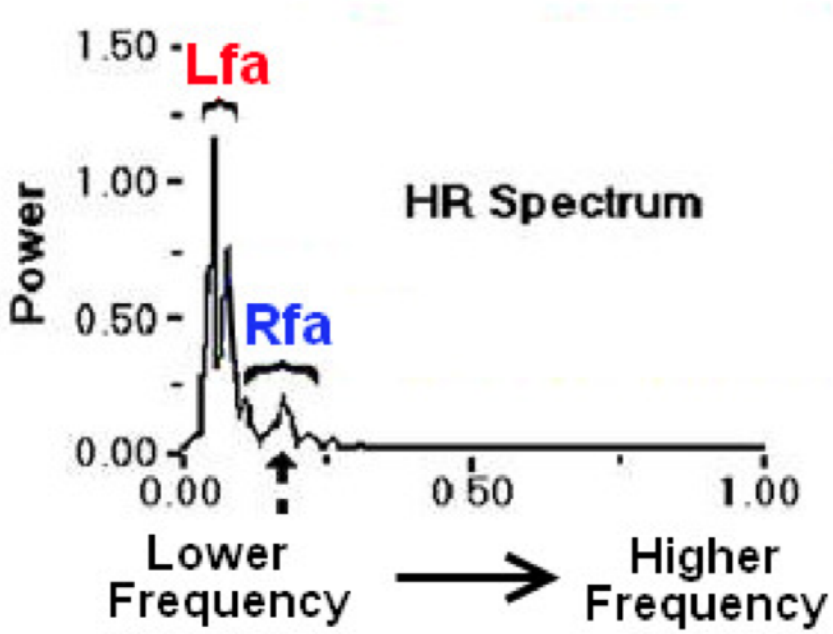

FIGURE 3-A2-Dimensional Heart Rate Power Spectrum. "Lfa" indicates the peaks corresponding to the low frequency area, "Rfa" indicates the peaks corresponding to the respiratory frequency area.

The power spectrum shows the frequencies at which events affecting the instantaneous heart rate or heart period occur. Further, the height of the peak in the power spectrum, power for this spectrum, reflects how many events of a given frequency, or given frequency range, occurred.

The power spectrum is limited in that it does not provide a power level for every frequency. Instead, the power spectrum provides average power for each of a series of frequency ranges—a factor referred to as frequency resolution. The frequency resolution is affected by the amount of time over which the data is analyzed and by how well the frequency analysis method "fits" with the signal data to which it is applied.

Referring to Fig. 2, the heart rate variability waveform appears to be, and in fact is, very irregular. Because of the irregularity, the heart rate variability waveform is described as "nonstationary". Fourier transforms, the common prior art method, assume that the analyzed data is stationary or quasi stationary (i.e. does not vary substantially over the period to be analyzed). Fourier transforms, by assuming data is stationary, do not "fit" particularly well to the nonstationary HRV waveform and, therefore, long time periods of HRV data must be used for the Fourier transform to generate a power spectrum with sufficiently reliable frequency resolution. Short-time Fourier transforms provide better frequency resolution than traditional Fourier transforms but still require data from relatively long time periods to generate power spectrums useful for ANS evaluation. Non-stationary signal analysis, including continuous wavelet transforms, are a better "fit" for the non-stationary heart rate variability data and heart rate power spectrums with sufficient frequency resolution can be generated using data from shorter time periods.

In addition, the non-stationary signal analysis methods of the '888 Patent, such as continuous wavelet transforms, allow the investigator to both detect a high percentage of the sympathetic ANS and parasympathetic ANS events that contribute to the heart rate variability and identify when those events occurred within a few seconds. The prior art methods either provide significantly less detail about the sympathetic ANS and parasympathetic ANS events (thereby providing less detail about ANS

functionality) or provide details for events in groups that occur over the range of about 1 minute or longer (preventing accurate correlation with the subject's activity). See e.g. the '888 Patent at 10:12-24 for discussion of testing procedures.

From the power spectrum, levels of activity for the sympathetic and for the parasympathetic ANS may be determined. Typically, the geometric areas under the identified peaks, Lfa and Rfa, respectively, reflect the activities of the sympathetic ANS and the parasympathetic ANS. The '888 Patent at 9:9-57.

The claimed methods and systems of the patents-in-suit disclose the use of a patient's respiration data to improve upon the quality of the ANS assessment. Id. at 8:65 to 9:8. The patient's respiration rate is measured through one of several possible methods, graphed and analyzed. Id. Figure 4 shows a graph of respiratory data.

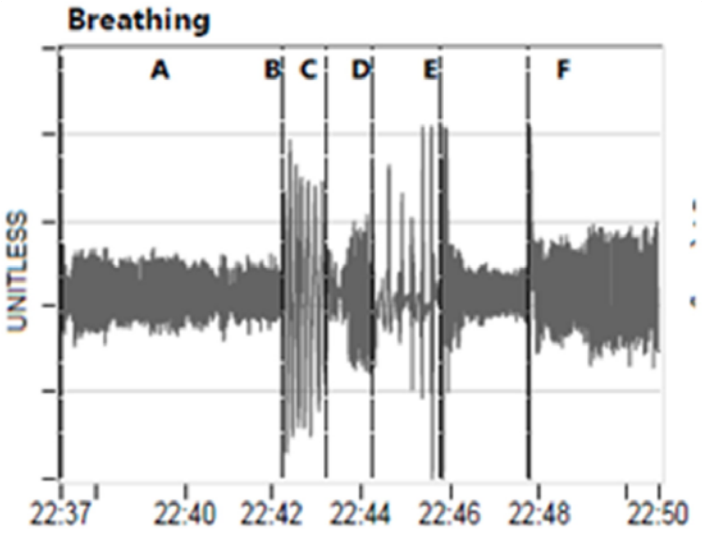

FIGURE 4

Breathing data such as that in Figure 4 is subjected to the same techniques (e.g. Fast Fourier Transform, Continuous Wavelet Transform as claimed in the '888 Patent, Short Time Fourier transform

as claimed in the '579 Patent) as used on the heart rate data. However, the power spectrum that results from the breathing data only provides information on the parasympathetic ANS and not the sympathetic ANS. The '888 Patent at 9:4-8 and 48-55. This is illustrated in Figure 5. The highest peak, labeled FRF in Figure 5, reveals the frequency associated with parasympathetic activity. The '888 Patent at 9:5-8.

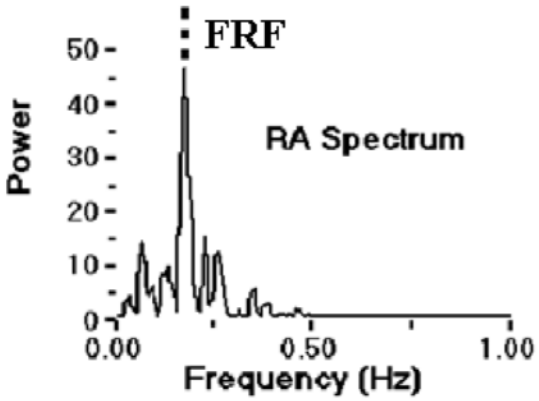

FIGURE 5

The heart rate power spectrum (Figure 3) and the RA (respiratory activity, Fig. 5) power spectrum are then compared to define the respiratory frequency area (Rfa) in the heart rate power spectrum. The '888 Patent at 9:48-52. This comparison is illustrated in Figure 6.

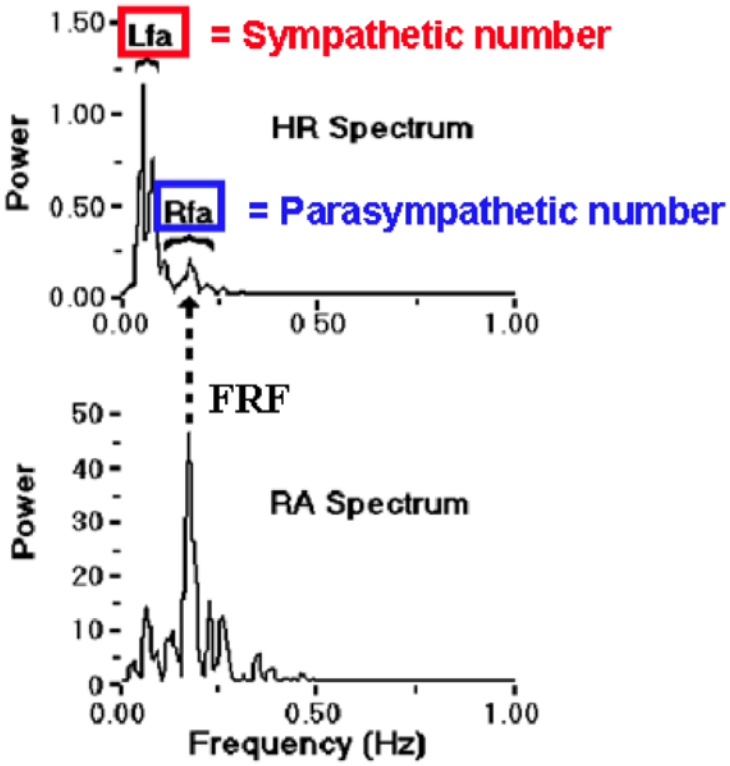

FIGURE 6

In this manner, a series of heart rate power spectra and respiratory activity power spectra are typically computed using data from a given subject. The ’888 Patent at 11:65–12:2 and 11:1-36. Using the preferred embodiment continuous wavelet transform of the ’888 patent, these spectra, and therefore the LFa and RFa, may be computed for each four seconds of data. The ’888 Patent at 11:65-67. For the short-time Fourier transforms described in the ’579 patent, LFa, and RFa may be calculated every 32 seconds. The ’579 Patent at 5:21-35. Other values which reflect the low frequency power (LF), high frequency power (HF), or respiratory frequency power (RP) may also be used to indicate the levels of sympathetic ANS activity, parasympathetic ANS activity, or some combination of both.

Once the LFa and RFa values have been calculated, they can be evaluated against control/normal values according to their changes over time and/or their changes in response to a challenge. The ’888

Patent at 10:51 to 11:18; the ’579 Patent at 6:39-55. Such comparisons can aid physicians in diagnosing and treating their patients. Id. The LFa reflects the activity of the sympathetic nervous system, while the RFa reflects the activity of parasympathetic nervous system. As noted above, other values may also be calculated that reflect the activities of the sympathetic ANS and parasympathetic ANS.

After levels of sympathetic ANS activity and parasympathetic ANS activity have been determined, such as by calculation of Lfa (sympathetic ANS activity) and Rfa (parasympathetic ANS activity), these levels may be compared to control/normal values from the general population or from the patient’s own data. *See e.g.*, discussion in the ’888 Patent, 10:49-11:18. For example, a drop in the patient’s Lfa upon standing may indicate orthostatic hypotension, a defect in the subject’s ability to compensate for the rush of blood downward when the subject stands. Id. at 11:9-14 Alternatively, an Rfa below the 15th percent of normal may indicate a defect in parasympathetic response. Id. at 10:57-62.

While the general subject matter of the patents-in-suit have similarities, the devices and methods of the ‘888 provide unique benefits related to evaluation of the ANS under specific challenges, such as a testing protocol designed to evaluate the ANS in an outpatient setting. ’888 Patent 10:9-24, 12:7-14. The methods and devices of the ’579 Patent provide benefits to evaluation of non-ambulatory patients when compared to certain methods of the ’888 patent, including methods using the continuous wavelet transforms. ’579 Patent 2:51-62.

B.

Again, the two patents-in-suit generally relate to systems for using real-time heart rate spectral analysis to monitor the autonomic nervous system. However, each provides a unique variation on the spectral analysis used to monitor the autonomic nervous system. The preferred embodiment of the ‘888 patent uses a continuous wavelet transform to perform this spectral analysis, whereas the preferred

embodiment of the '579 patent uses short-term Fourier Transforms in conjunction with a modified Bartlett window scheme to perform this spectral analysis

C.

The '888 Patent was issued to Plaintiffs by the U.S. Patent and Trademark Office ("the USPTO",) on July 18, 2006. The '579 Patent was issued by the USPTO on May 5, 2009. Neither of these patents has been subjected to any post-grant review, such as reissue or reexamination, nor has either of the patents been construed by another Court.

On February 29, 2012, Plaintiff filed suit in the United States District Court in and for the Southern District of Texas, alleging patent infringement. (Instrument No. 1). Specifically, Plaintiff claims that Defendants, Medeia, Inc., Medeia, Ltd., Critical Patient Care, Inc., and Marie Cosgrove (collectively "Defendants"), have infringed and continue to infringe Claims 1, 2, 4 and 21, of the '888 Patent and Claim 1 of the '579 Patent by making, using, selling, offering to sell or importing the Critical Care Assessment and QHRV-1 products and software. Claims 1, 2, and 4 of the '888 Patent and Claim 1 of the '579 Patent are method claims, while Claim 21 of the '888 Patent is a system claim. *See* (Instrument No. 44).

On June 7, 2013, in anticipation of the *Markman* hearing, the Plaintiff submitted its initial position paper, Plaintiff's Second Opening Claim Construction Brief (Instrument No. 163), stating its positions on each of the terms in dispute in this case. On June 21, 2013, Defendants filed their Second Responsive Claim Construction Brief, (Instrument No. 165), wherein the defendants proffered their own definitions of all the terms in dispute. On June 28, 2012, Plaintiff filed a reply brief on claim construction, responding to the contentions made in the defendants' responsive pleading. (Instrument

No. 166). On July 16, 2013, the Court held a *Markman* hearing, at which the parties' debated the meaning of the contested terms.

D.

The parties' dispute centers on the meaning of terms contained in the two patents-in-suit. The parties contest the meaning of nine terms contained in the '888 patent and two terms contained in the '579 patent.

1.

a.

The plaintiff and defendants, collectively, have asserted claims of infringement and non-infringement, respectively, for claims 1, 2, 4, and 21 of the'888 Patent.

The first asserted claim, claim 1, describes a method for measuring activity of the autonomous nervous system of a patient comprising the steps of:

> 1) obtaining instantaneous heart rate signals of said patient;
> 2) computing a first power spectrum from said instantaneous heart rate signals using non-stationary signal analysis;
> 3) determining a level of sympathetic activity and parasympathetic activity from said power spectrum;
> 4) obtaining respiratory activity signals of said patient;
> 5) computing a second power spectrum from said respiratory signals using non-stationary signal analysis; and,
> 6) determining the instantaneous respiration frequency from the said second power spectrum.

(Instrument No. 163-2, at 12 ¶ 12: 23-37). In claim 1, the parties dispute the meaning of the terms: (i) determining a level of sympathetic activity and parasympathetic activity; (ii) respiratory activity signals; (iii) non-stationary signal analysis.

The second asserted claim, claim 2, describes a method as set forth in claim 1, further comprising the steps of:

> 7) computing a low frequency area from said first power spectrum
> 8) computing a respiration frequency area from said second power spectrum
> 9) using said low frequency area to determine a level of sympathetic activity
> 10) using said respiration frequency area to determine a level of parasympathetic activity; and
> 11) using the ratio of said low frequency area to said respiration frequency area to determine a level of sympathovagal balance.

(Instrument No. 163-2, at 12 ¶ 12: 38-41). In claim 2, the parties dispute the meaning of the terms: (i) low frequency area; (ii) respiration frequency area; (iii) level of parasympathetic activity; and (iv) level of sympathovagal balance.

The third asserted claim, claim 4, describes "a method as set forth in claim 2, wherein step 2 and step 5 comprise computing said first power spectrum and said second power spectrum using analysis windows of four seconds or less." (Instrument No. 163-2, at 12 ¶ 12: 54-57). The parties do not dispute the meaning of any terms included in claim 4.

The fourth asserted claim, claim 21, describes a system for measuring activity of the autonomous nervous system of a patient comprising:

> a first source providing instantaneous heart rate signals of said patient;
> a signal processor coupled to said first source, said processor used to compute
> a first power spectrum of said heart rate signal using continuous wavelet transform techniques;
> an output coupled to said signal processor, said output providing a visual display of said first power spectrum;
> and a second source providing instantaneous respiration signals, wherein said signals are processed by said processor to obtain a second power spectrum, said second spectrum displayed on said output.

(Instrument No. 163-2, at 13 ¶ 14: 20-34). In claim 4, the parties dispute the meaning of the terms: (i) continuous wavelet transform and (ii) coupled.

b.

In total, the parties contest the meaning of nine terms contained in the '888 patent.The table below summarizes the nine disputed claim terms contained in claims 1, 2, and 21 of the '888 patent and the parties' proposed constructions of the disputed language.

#	Patent & Claim	Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
1	'888, clm. 1	[determining] a level of sympathetic and parasympathetic activity	[determining] a level for the activity of the sympathetic branch of the autonomic nervous system (ANS) and for the parasympathetic branch of the ANS. The sympathetic branch, among other things, raises heart rate and blood pressure while the parasympathetic branch, among other things, lowers heart rate and blood pressure. **Alternative:** A value for the sympathetic nervous system reflecting its activity and a value for the parasympathetic nervous system reflecting its activity.	Determining] (1) energy in the heart rate power spectrum between 0.04 and 0.1 Hz and (2) energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration. **Alternative:** (1) energy in the power spectrum in the frequency range from 0.04 Hz to 0.15 Hz (LF); (2) energy in the frequency range from 0.15 to 0.4 Hz (HF) so long as the respiratory frequency remains above 0.15 Hz; and (3) the ratio of LF/HF so long as the respiratory frequency remains above 0.15 Hz.

#	Patent & Claim	Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
2	'888, clm. 1	[using] nonstationary signal analysis	signal analysis methods that provide the necessary time resolution at higher frequencies and the necessary frequency resolution at low frequencies to enable independent determination of activity levels.	continuous wavelet transform **Alternate:** signal analysis that (1) avoids the time frequency compromise of Fast Fourier Transforms, autoregressive techniques, and Short- Term Fourier Transforms and (2) permits the implementation of very short signal analysis periods
3	'888, clm. 1	respiratory activity signals	No construction necessary	signals obtained from an impedance pneumography source
4	'888, clm. 21	continuous wavelet transform	A signal processing method for converting time domain signal data into frequency domain signal data by breaking the time domain data into smaller sections and transforming each section using translations and amplifications of a chosen wavelet. Continuous wavelet transform techniques include the use of computer hardware and software solutions for computing the result of such a transform. Continuous wavelet transforms may be represented generally by the expression $CWT(n, f) = \Delta t \; k(s) \sum_{\mu} x(\mu) \; h^{*}((n - \mu)/s \bullet \Delta t)$, for $s = f0/f$	The agreed mathematical expression below, plus: The continuous wavelet transform possesses the ability to construct a time frequency representation of a signal that offers very good time and frequency localization. $CWT(n, f) = \Delta t \; k(s) \sum_{\mu} x(\mu) \; h^{*}((n - \mu)/s \bullet \Delta t)$, for $s = f0/f$ whereby: $x(\mu)$ = a small section of any time-domain data h = any "mother" wavelet Δt is the sampling period; $k(s)$ is a normalizing parameter that depends on the scale factor 's'; * represents complex conjugate; and $f0$ is a constant reference

#	Patent & Claim	Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
5	'888, clm. 2	low frequency area	The energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz, excluding any portion of the selected frequency range that overlaps the frequency range used in calculating the Respiratory Frequency area.	Energy in the power spectrum in the frequency range from 0.04 Hz to 0.1 Hz.
6	'888, clm. 2	respiration frequency area	Energy in the heart rate power spectrum in a range of frequencies containing the respiration peak frequency that is scaled to the value of the respiration peak frequency	Energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration
7	'888, clm. 2	a level of sympathovagal balance	a level of the balance of the sympathetic system and the parasympathetic system	The ratio LFa/RFa.
8	'888, clm. 2	a level of sympathetic activity	construed under claim 1; no construction necessary	energy in the heart rate power spectrum between 0.04 and 0.1 Hz
		a level of parasympathetic activity	construed under claim 1, no construction necessary	energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration
9	'888, clm. 2	coupled	No construction necessary Alternative: "Linked, accompanied, associated"	Linked

2.

a.

The plaintiff has asserted a claim of infringement for claim 1 of the '579 Patent. Claim 1 describes a method for power spectral analysis of heart rate variability comprising the steps of:

> capturing a sample set of spline-interpolated heartbeat EKG signals;
> applying a modified Bartlett window to a waveform of the captured sample set;
> subjecting the windowed waveform to short-time Fourier transform (STFT);
> and isolating a respiratory frequency area (RFA) from a low frequency area (LFA).

(Instrument No. 163-3, at 16 ¶ 8: 26-35). In claim 1, the parties dispute the meaning of the terms: (i) modified Bartlett window; (ii) low frequency area; and (iii) respiratory frequency area.

b.

In total, the parties contest the meaning of three terms contained in the '579 patent. The table below summarizes the nine disputed claim terms contained in claim 1 of the '579 patent and the parties' proposed constructions of the disputed language.

#	Patent & Claim	Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
1	'579, clm. 1	modified Bartlett window	A mathematical function that may be represented by a modified triangle and is useful for windowing, selecting a range of a signal for analysis, while emphasizing certain data within that range and minimizing other data within the range	A window as shown in Figure 6, 7, or 8 of the '579 patent
2	'579, clm. 1	low frequency area	The energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz, excluding any portion of the selected frequency range that overlaps the frequency range used in calculating the Respiratory Frequency area	Energy in the power spectrum in the frequency range from 0.04 Hz to 0.1 Hz.

E.

Prior to the *Markman* hearing, the parties exchanged proposed terms and definitions to identify, first, those terms whose definitions could not be agreed upon and therefore required construction by the Court and, second, those terms where the parties could agree upon a definition. The chart below represents the list of agreed upon terms:

U.S. Patent No. 7, 079, 888 (the '888 Patent)

#	Patent & Claim	Claim Term	Agreed Upon Construction
1	'888, clm. 21	signal processor	A device which processes signals containing information.
2	'888, clm. 1	power spectrum	A representation of the portion of a signal's energy falling within given frequency bins as a function of time, the frequency (or scale or dilation as it is also known) represented on one axis and the energy (or location or shift as it is also known) represented on another. Such power spectra may be two dimensional or three dimensional with the time factor incorporated by, in two dimensions, expressing the energy as power (energy per unit of time) and plotting the power on one axis and the frequency on the other axis or in three dimensions, by plotting energy on one axis, frequency on another axis and time on the third axis.
3	'888, clm. 1	source	An input signal obtained from the body of an individual being monitored, which may comprise one of heart rate and respiratory function, but is not limited thereto.
4	'888, clm. 1	signal analysis	The process of breaking a signal down into one or more of its components, such as amplitude, phase and frequency.
5	'888, clm. 1 and 21	instantaneous heart rate signals	Subject data from which the heart rate of two adjacent heartbeats may be determined.
6	'888, clm. 1 and 21	instantaneous respiration signals	Subject data from which the breathing rate of two adjacent breaths may be determined.
7	'888, clm. 4	analysis window	The length of time from which data is used to perform or update the signal analysis.

U.S. Patent No. 7, 529,579 (the '579 Patent)

#	Patent & Claim	Claim Term	Agreed Upon Construction
1	'579, clm. 1	waveform	The shape of a graph of a wave or the oscillation waveform The shape of a graph of a wave or the oscillation
2	'579, clm. 1	isolating	separating
3	'579, clm. 1	spline-interpolated	A method of constructing new data points within the range of a discrete set of known data points; spline interpolation is a form of interpolation where the interpolant, or interpolated data, is a special type of mathematical expression of finite length called a spline; a spline is a mathematical expression that is piecewise-defined and possesses a high degree of smoothness at the places where the pieces connect.
4	'579, clm. 1	short-time Fourier transform	Fourier transform of signal data after the data has been multiplied by a windowing function.

II.

A.

Whoever without authority makes, uses, or sells any patented invention within the United States during the term of the patent therefor, infringes the patent. 35 U.S.C. § 271. The determination of whether a claim of a patent has been infringed is a two-step process. First, the Court must determine the meaning and scope of the patent claims asserted to be infringed. *See Bell Atl. Network Servs., Inc. v. Covad Comms. Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd,* 116 S. Ct. 1384 (1996). This step is commonly known as claim construction or interpretation. Claim construction, including the construction of terms of art within a claim, is a matter of law "exclusively within the province of the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). Second, the court must compare the claims alleged to be

infringed to the accused device. *See Bell Atlantic*, 262 F.3d at 1267; *Markman*, 52 F.3d at 976. This second-step is a factual determination reserved for the trier-of-fact. *Cook Biotech, Inc. v. Acell, Inc.*, 460 F.3d 1365, 1373 (Fed Cir. 2006); *Middleton, Inc. v. Minn. Mining & Mfg. Co.*, 311 F.3d 1384, 1387 (Fed. Cir. 2002).

The standards governing claim construction are well established. "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). The goal of a *Markman* hearing is to arrive at the ordinary and customary meaning of a claim term in the eyes of a person of ordinary skill in the art. *Phillips*, 415 F.3d at 1313. Proper claim construction demands interpretation of the entire claim in context, not a single element in isolation. *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1347 (Fed. Cir. 2008) ("claim terms [are not construed] in a vacuum, devoid of the context of the claim as a whole."); *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999). Accordingly, "the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." *Phillips*, 415 F.3d at 1316.

When construing a claim, "the words of a claim are generally given their ordinary and customary meaning." *Phillips*, 415 F.3d at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Kyocera*, 545 F.3d at 1346. The ordinary and customary meaning of claim "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313. "[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention,

unless the text of the patent makes clear that a word was used with a special meaning." *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299 (Fed. Cir. 1999). Thus, "unless compelled to do otherwise, a court will give a claim term the full range of its ordinary meaning as understood by an artisan of ordinary skill." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001).

In some cases, "the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips,* 415 F.3d at 1314. Where, however, the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone, the court must look to "sources available to the public that show what a person of skill in the art would have understood [the] disputed claim language to mean." *Phillips,* 415 F.3d at 1314.

1.

When construing this latter category of claims, the Court first looks to intrinsic evidence of claim meaning "*i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics*, 90 F.3d at 1582. The "intrinsic record in a patent case is the primary tool to supply the context for interpretation of disputed claim terms," because the intrinsic record "provides the technological and temporal context to enable the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of invention." *V-Formation, Inc. v. Benetton Group SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1370 (Fed. Cir. 2005). Accordingly, the interpretation of a claim term "should be harmonized, to the extent possible, with the intrinsic record, as understood within the technological field of the invention," *Lexicon Medical, LLC v. Northgate Tech., Inc*., 641 F.3d 1352, 1356 (Fed. Cir. 2011).

a.

In reviewing the intrinsic record, the court must first "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Vitronics*, 90 F.3d at 1582; *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1358 (Fed. Cir. 2012). Given that the "claims define the patent right naturally the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed Cir. 2009). As such, the "context in which a term is used in the asserted claim can be highly instructive." *Phillips*, 415 F.3d at 1314. Similarly, the relationship between the asserted claim and other claims can provide additional instruction because "terms are normally used consistently throughout the patent." *Phillips*, 415 F.3d at 1314. Thus, "usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314. Finally, the "[d]ifferences among claims can also be a useful guide" when discerning the meaning of a particular claim term. *Phillips*, 415 F.3d at 1314. Thus, claim language and the context in which that language arises can be illustrative and often "provide[s] a firm basis for construing [a challenged] term." *Phillips*, 415 F.3d at 1314.

b.

The claims and the claim language, of course, do not stand alone. Rather, "they are part of a fully integrated written instrument, consisting principally of a specification that concludes with the claims." *Phillips*, 415 F.3d at 1315. "In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention." *Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004). Therefore, the "claims must be read in view of the specification, of which they are a part." *Phillips*, 415 F.3d at 1315; *Abbott Labs*, 566 F.3d at 1288 (the specification "is always highly relevant to the claim construction analysis").

The review of the specification may reveal, for example, that the patentee has defined his own terms or given a claim term a different meaning that it would otherwise possess. *Phillips*, 415 F.3d at 1316. In such cases, "the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). On other occasions, "the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Phillips*, 415 F.3d at 1316. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is dispositive. *Phillips*, 415 F.3d at 1316. Given the nuance supplied by the specification, the "construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips*, 415 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Società per Azioni*, 158 F.3d, 1243, 1250 (Fed. Cir. 1998) (citations omitted)).

That said, when consulting the specification to clarify the meaning of a disputed term, the Court must take care not to import limitations into the claims from the specification. *Abbott Labs*, 566 F.3d at 1288. A patent is not restricted to the preferred embodiments or examples provided in the intrinsic record, but rather the patent is defined by the words of the claims. *See Liebel-Flarsheim Co. v. Medrad, Inc.,* 358 F.3d 898, 906 -10 (Fed. Cir. 2004)*; Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988). Thus, for example, "when the specification describes a single embodiment to enable the invention, th[e] court will not limit broader claim language to that single application" unless the patentee has demonstrated that the claims themselves, the specification, or the prosecution history "clearly indicate that the invention encompasses no more than that confined structure or method." *Abbott Labs*, 566 F.3d at 1288.

c.

The prosecution history is the final interpretative tool in the intrinsic record. *See Phillips*, 415 F.3d at 1317. The prosecution history includes "all express representations made by or on behalf of the applicant to the examiner to induce a patent grant, or . . . to reissue a patent . . . includ[ing] amendments to the claims and arguments made to convince the examiner that the claimed invention meets the statutory requirements of novelty, utility, and nonobviousness." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985); *see also Phillips*, 415 F.3d at 1317. The prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317 (citing *Vitronics*, 90 F.3d at 1582–83).[1] Although, the prosecution history may be informative on how the inventor and the Patent Office understood the patent, it is often less useful than the specification because the prosecution history is the fruit of negotiations between the inventor and Patent Office. As such, the prosecution history lacks the clarity of the final specification. *Phillips*, 415 F.3d at 1317. Accordingly, the "claim language and the specification generally carry greater weight than the prosecution history." *HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1276 (Fed. Cir. 2012).

[1] Under the doctrine of prosecution disclaimer, for example, the patentee may be precluded from recapturing through claim interpretation specific meanings disclaimed during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (citing cases). The doctrine is only invoked where the patentee clearly and unambiguously disclaimed or disavowed the proposed interpretation during prosecution to obtain claim allowance. *Middleton Inc. v. 3M Co.*, 311 F.3d 1384, 1388 (Fed. Cir. 2002); *see also Phillips*, 415 F.3d at 1325 (only when "the patentee has unequivocally disavowed a certain meaning to obtain his patent [does] the doctrine of prosecution disclaimer attach[] and narrow the ordinary meaning of the claim congruent with the scope of the surrender"). The doctrine of prosecution disclaimer has become a basic principle of claim interpretation because it "promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." *Omega Eng'g, Inc.,* 334 F.3d at 1324.

2.

"In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Vitronics*, 90 F.3d at 1582. If the intrinsic evidence is clear, "it is improper to rely on extrinsic evidence in construing the patent claims." *Vitronics*, 90 F.3d at 1582. Where ambiguity persists the court may "rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317 (quoting *Markman*, 52 F.3d at 980). Extrinsic evidence, however, is "in general . . . less reliable than the patent and its prosecution history" because it is not part of the patent and may not have been created at the time of the patent's prosecution; extrinsic publications may not have been written by or for skilled artisans; and expert reports and testimony created at the time of litigation may suffer from bias not present in intrinsic evidence. *Phillips*, 415 F.3d at 1318.

Extrinsic evidence is therefore "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317. Accordingly, "the general meanings gleaned from reference sources, such as dictionaries [and treatises], must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor." *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.,* 334 F.3d 1294, 1300 (Fed. Cir. 2003); *see also Wavetronix v. EIS Elec. Integrated Sys.,*573 F.3d 1343, 1355 (Fed. Cir. 2009). Otherwise, dictionary definitions will effectively be "converted into technical terms of art having legal, not linguistic, significance," *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998), relegating the intrinsic evidence to a mere "check on the dictionary meaning of a claim term." *Phillips*, 415 F.3d at 1320. In light of these considerations, extrinsic evidence is primarily used to

facilitate "the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Markman*, 52 F.3d at 981.

B.

In construing the claim terms, the court must also determine whether any claim terms are invalid due to indefiniteness. 35 U.S.C. § 112, P 2 requires that a patent specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, P 2. "[T]he purpose of th[is] definiteness requirement is to ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005); *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1352 (Fed. Cir. 2009).

"The definiteness requirement, however, does not compel absolute clarity." *Datamize*, 417 F.3d at 1347 (internal quotations omitted). This definiteness requirement is satisfied "[i]f one skilled in the art would understand the bounds of the claim when read in light of the specification." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001); *IGT v. Bally Gaming Int'l, Inc.,* 659 F.3d 1109, 1119 (Fed. Cir. 2011). Where "the meaning of the claim is discernable, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, . . . the claim [is] sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon*, 265 F.3d at 1375; *Honeywell Int'l, Inc. v. United States*, 609 F.3d 1292, 1301 (Fed. Cir. 2010).

An issued claim is presumed valid under 35 U.S.C. § 282 and is not indefinite unless it "is insolubly ambiguous, and no narrowing construction can properly be adopted." *Exxon*, 265 F.3d at 1375; *Honeywell*, 609 F.3d at 1301. To prove indefiniteness, the accused infringer must "demonstrate by clear

and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art." *Wellman, Inc. v. Eastman Chem. Co*., 642 F.3d 1355, 1366 (Fed. Cir. 2011). "Because claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet an exacting standard." *Wellman*, 642 F.3d at 1366. Thus, all "close questions of indefiniteness…are properly resolved in favor of the patentee." *Ergo Licensing, LLC v. CareFusion 303, Inc.,* 673 F.3d 1361, 1367 (Fed. Cir. 2012).

III.

The Court will now apply these general principles of claim construction to the terms at issue here.

A.

Term No. 1: "[determining] a level of sympathetic and parasympathetic activity" (claim 1)

Disputed Term	Plaintiff's Proposed Construction	Defendant's Proposed Construction
[determining] a level of sympathetic and parasympathetic activity	[determining] a level for the activity of the sympathetic branch of the autonomic nervous system (ANS) and for the parasympathetic branch of the ANS. The sympathetic branch, among other things, raises heart rate and blood pressure while the parasympathetic branch, among other things, lowers heart rate and blood pressure. **Alternative:** A value for the sympathetic nervous system reflecting its activity and a value for the parasympathetic nervous system reflecting its activity.	Determining (1) energy in the heart rate power spectrum between 0.04 and 0.1 Hz and (2) energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration. **Alternative:** (1) energy in the power spectrum in the frequency range from 0.04 Hz to 0.15 Hz (LF); (2) energy in the frequency range from 0.15 to 0.4 Hz (HF) so long as the respiratory frequency remains above 0.15 Hz; and (3) the ratio of LF/HF so long as the respiratory frequency remains above 0.15 Hz.

a.

The first disputed term of the '888 Patent is "[determining] a level of sympathetic and parasympathetic activity." According to Plaintiff, the term should be construed to mean "[determining] a level for the activity of the sympathetic branch of the autonomic nervous system (ANS) and for the parasympathetic branch of the ANS. The sympathetic branch, among other things, raises heart rate and blood pressure while the parasympathetic branch, among other things, lowers heart rate and blood

pressure." (Instrument No. 163, at 18). According to Plaintiff, this definition is firmly supported by the patent specification and also comports with the ordinary and plain meaning of the term, as understood by a person of ordinary skill in the art. *See* (Instrument No. 163, at 18 -21).

In support of its construction, Plaintiff notes that the '888 Patent specification identifies a need for "a non-invasive method of analyzing biological data . . .to provide accurate, meaningful, autonomic nervous system assessment from real time heart rate variability data." (Instrument No. 163-2, at 8 ¶ 3:41-44). To meet this objective, patient data, such as heart rate data and respiratory activity data, is collected and analyzed to determine the subject's sympathetic and parasympathetic ANS activity levels under varying test conditions. *See e.g.,* (Instrument No. 163-2, at 11 ¶ 10:9-28). The patent further provides that the activity levels determined by the claimed inventions may be evaluated by comparison to established standards and may also be evaluated according to how the sympathetic and parasympathetic activity levels change in response to the test conditions. (Instrument No. 163-2, at 11 ¶ 10:34-43). Accordingly, Plaintiff contends that the disputed phrase "level of sympathetic and parasympathetic activity" is simply a measure or value that may be compared to known standards and/or levels from the same subject at a different time or under different conditions. (Instrument No. 163, at 19).

Defendants, however, contend that the term "[determining] a level of sympathetic and parasympathetic activity" should be defined to mean "determining] (1) energy in the heart rate power spectrum between 0.04 and 0.1 Hz and (2) energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration." (Instrument No. 165, at 5-6). According to the defendants, claim 1 of the '888 patent, relates to a "method for measuring activity of the autonomous nervous system of a patient," where one

of the steps of the claimed method requires the determination of "a level of sympathetic and parasympathetic activity from [a] power spectrum [derived from an instantaneous heart signal] (heart rate power spectrum)" (Instrument No. 163-2, at 12 ¶ 12: 23-24; 12: 30-31). In the description of the invention, the patentee explains that activity in the sympathetic and parasympathetic may be discerned from energy activity in the heart rate power spectrum, because the heart rate power spectrum features two unique areas: a low frequency area, or an LFa, which corresponds to energy in the heart rate power spectrum between 0.04 and 0.1 Hz, and a respiration frequency area, or an RFa, which is defined as energy in the heart rate power spectrum under the respiration peak frequency, calculated using a window whose bandwidth is proportional to the frequency of respiration. (Instrument No. 163-2, at 11 ¶ 12:27-28; 11 ¶ 9: 45-52). The specification further explains that the low frequency area is "indicative of the activity in the sympathetic system" while RFa is "indicative of the activity in the parasympathetic system." (Instrument No. 163-2, at 12 ¶ 12:27-28; 11 ¶ 9: 47-48; 54-55). Accordingly, defendant contends that determining a "[determining] a level of sympathetic and parasympathetic activity," requires one to (1) determine a level of sympathetic activity by determining LFa ("energy in the heart rate power spectrum between 0.04 and 0.1 Hz") and (2) determine a level of parasympathetic activity by determining RFa ("energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration"), which is the defendants' construction. (Instrument No. 165, at 6).

Defendants recognize that their construction is narrow, but insist that this construction is compelled by the specification because: (i) the patent specification only details two methods for determining a level of sympathetic and parasympathetic activity, the preferred method, described above, involving the extraction of the LFa and RFa of the heart rate power spectrum, and a prior method, and

(ii) the specification then states that the preferred method distinguishes the '888 patent from the prior art. (Instrument No. 165, at 8). Defendants contend that this requires that the disputed claim be limited in scope to the method disclosed in the preferred method. (Instrument No. 165, at 8).

In the Reply, Plaintiff contends that Defendants construction improperly substitutes the claim phrase "sympathetic activity" with the term "low frequency area" and the claim phrase "parasympathetic activity" with the term "respiratory frequency area" and then reads limitations from the specification into the construction of the substituted terms. (Instrument No. 166, at 4). According to Plaintiff, Defendants' substitution of terms is improper because the specification clearly states that the LFa is "indicative" of sympathetic activity and that the RFa is "indicative" of parasympathetic activity; the specification does not limit sympathetic activity to energy occurring in the LFa nor does it limit parasympathetic activity to energy occurring in the RFa. (Instrument No. 166, at 5). Plaintiff further contends that the defendants construction is further flawed by equating the LFa to one of the examples in the preferred embodiment, where the LFa "is computed as the energy in the heart rate power spectrum between 0.04 and 0.1 Hz." (Instrument No. 166, at 5).

Plaintiff also contends that the defendants' reading is improper because it violates the principle of claim differentiation. (Instrument No. 163, at 19). Claim 2 of the '888 patent, which depends from Claim 1, contains the elements "using said low frequency area to determine a level of sympathetic activity" and "using said respiration frequency area to determine a level of parasympathetic activity". (Instrument No. 163-2, at 12 ¶ 12:37-50.). Under defendants' construction, there is no distinction between the scope of claim 1 and claim 2. However, under the doctrine of claim differentiation, each claim in a patent is presumptively different in scope. According to Plaintiff, the defendants' construction violates this presumption and is therefore invalid. (Instrument No. 163, at 20-21).

b.

In essence, the parties' dispute regarding the construction of the term "[determining] a level of sympathetic and parasympathetic activity" centers on whether the plaintiff has disavowed any construction of the term beyond that disclosed in the preferred embodiment, such that the term should be limited to the description contained in the discussion of the preferred embodiment.

As the parties' dispute centers on the limiting effect of the patent specification, the Court turns now to the specification. It is an elementary principle of claim construction that when consulting the specification to clarify the meaning of a disputed term, the Court must take care not to import limitations into the claims from the specification. *Abbott Labs*, 566 F.3d at 1288. A patent is not restricted to the preferred embodiments or examples provided in the intrinsic record, but rather the patent is defined by the words of the claims. *See Medrad, Inc.,* 358 F.3d at 906 -10*; Specialty Composites*, 845 F.2d at 987. Thus, for example, even "when the specification describes a single embodiment to enable the invention, th[e] court will not limit broader claim language to that single application" unless the patentee has demonstrated that the claims themselves, the specification, or the prosecution history "clearly indicate that the invention encompasses no more than that confined structure or method." *Abbott Labs*, 566 F.3d at 1288.

In this case, Defendants unabashedly ask this Court to limit the scope of the claim language to the application disclosed in the preferred embodiment, but fail to point to any evidence in the intrinsic record that demonstrates that the patentee intended such. Defendant contends that the disputed term should be construed to mean determining] (1) energy in the heart rate power spectrum between 0.04 and 0.1 Hz and (2) energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration" because the

specification teaches that the heart rate power spectrum features two unique areas, an LFa and an RFa, where energy in the LFa is indicative of activity in the sympathetic system and energy in the RFa is indicative of activity in the parasympathetic system. (Instrument No. 165, at 4-6).

First, assuming that the patentee intended to limit the scope of the claim language to the disclosed preferred embodiment, the mere fact that the specification teaches that activity in the LFa is indicative of activity in the sympathetic system and activity in the RFa is indicative of activity in the parasympathetic system, does not mean that the activity in the sympathetic system is coterminous with activity in the LFa nor does it mean that activity in the parasympathetic system is conterminous with activity in the RFa.

Second, there is no evidence that the patentee intended to limit the claim to the preferred embodiment; the defendant has not pointed to any evidence in the claims, patent specification, or prosecution history demonstrating an intention to limit the claim language to the methods disclosed in the preferred embodiment.

On review, the Court finds that the defendants' proposed and alternate constructions improperly import limitations from the preferred embodiment into the claim language. Accordingly, the Court rejects the defendants' construction. However, the plaintiff's construction is also lacking. The plaintiff's proposed definition does not substantively define the disputed term; it uses the term "level" to define "level" As such, the plaintiff's proposed definition does not provide further instruction on the scope of the disputed and therefore should not be adopted. That said, the plaintiff's alternative definition does not suffer from this defect. The alternative construction seeks to define the term " [determining] a level of sympathetic and parasympathetic activity" to mean "a value for the sympathetic nervous system reflecting its activity and a value for the parasympathetic nervous system reflecting its activity." This

definition comports with the plain meaning of the term, as understood by someone in the art, it is clear and concise, and adheres to the teachings of the specification which instructs that the levels of sympathetic activity are values that indicate sympathetic activity and that the levels of parasympathetic activity are values that indicate parasympathetic activity. *See* (Instrument No. 163-2, at 11 ¶ 10: 9-50).

Term No. 2: "[using] nonstationary signal analysis" (claim 1)

Disputed Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**
[using] nonstationary signal analysis	signal analysis methods that provide the necessary time resolution at higher frequencies and the necessary frequency resolution at low frequencies to enable independent determination of activity levels.	continuous wavelet transform **Alternate:** signal analysis that (1) avoids the time frequency compromise of Fast Fourier Transforms, autoregressive techniques, and Short- Term Fourier Transforms and (2) permits the implementation of very short signal analysis periods

a.

The second disputed term of the '888 Patent is "[using] nonstationary signal analysis." According to Plaintiff, the term should be construed to mean "using signal analysis methods that allow for the time varying nature of a variable signal where the variability indicates different activities and the signal analysis period can be less than 32 seconds." (Instrument No. 163, at 21). According to Plaintiffs, non-stationary signal analysis is a term known in the art that encompasses methods for analyzing signals that are not stationary—i.e., signals that are both not infinite and not repeated periodically, but vary over time. (Instrument No. 163, at 21). Accordingly, Plaintiff contends that its construction should be adopted.

Defendants, however, contend that the disputed term "[using] nonstationary signal analysis" should be construed to mean "continuous wavelet transform." (Instrument No. 165, at 10). According to

defendants the novelty of this invention rests in its ability to allow for non-stationary signal analysis of biological data: the patent explains that stationary signal analysis, such as frequency-domain analysis, involves a time-frequency compromise whereby increasing the frequency resolution of the analysis results in a deterioration in the time analysis resolution and improving the time-analysis resolution compromises the frequency resolution, thereby limiting the utility of non-stationary signal analysis for the processing of the type of biological data contemplated by the patent.(instrument No. 165, at 10-11). The patent then explains that the "non-stationary signal analysis of biological signal avoids the time-frequency compromise and permits the implementation of very short signal analysis." (Instrument No. 163-2, at 12 ¶ 11: 63-65). The patent further explains that by avoiding this time-frequency compromise, non-stationary signal analysis "provides better time- and frequency-resolution of biological signals," which "enables a better separation in the monitoring of the two autonomic nervous system branches," a practical benefit not shared by prior methods of signal analysis, including "FFT, autoregression [AR], or short-time FFT analysis." (Instrument No. 163-2, at 11 ¶ 13: 52- 62).

Accordingly, the defendants contend that the term "non-stationary signal analysis" must, at a minimum, be defined in way that it excludes FFT, AR, and short-time FFT methods and only includes those signal analysis methods that (1) avoid the "time-frequency" compromise and (2) enable the use of short signal analysis periods. (Instrument No. 165, at 11-12). In this case, though, the defendants contend that the term should be limited even further to mean "continuous wavelet transforms." (Instrument No. 165, at 12). According to defendants, this reading is proper because: (i) the summary of the invention section specifically states that "the present invention applies the technique of continuous wavelet transformation to input signals obtained from various physiological sensors" and the inclusion of this language in the summary of the invention limits the entire scope of the patent to the continuous

wavelet transforms and (ii) besides the disclosure of the continuous wavelet transforms, the patent does not cite or teach any other form of non-stationary signal analysis appropriate for use with biological signals

Plaintiff contends that Defendants' proposed construction violates the claim differentiation presumption because it diminishes all distinction between claim 1 and claim 15 of the '888 Patent; Claim 1 uses the broader term "nonstationary signal analysis," while dependent Claim 15 specifically claims that "said nonstationary signal analysis used in step 5 is continuous wavelet transforms." (Instrument No. 163-2, at 12 ¶ 12:33-34; 13 ¶ 14:1-3). Accordingly, Plaintiff contends that defining the term "nonstationary signal analysis" in term one as "continuous wavelet transform" improperly imports a limitation from claim 15 into the interpretation of claim 1, such that the scope of claim 1 is coterminous with the scope of claim 15. *See* (Instrument No. 163, at 22); (Instrument No. 166, at 6). Moreover, Plaintiff objects to alternative construction because it unnecessary excludes Fast Fourier Transforms, autoregressive techniques, and Short-term Fourier Transforms from the canon of techniques that could be used to perform the non-stationary signal analysis. (Instrument No. 166, at 6).

b.

The parties' dispute regarding the construction of the term "[using] nonstationary signal analysis" centers on whether the plaintiff has disavowed any construction of the term beyond that disclosed in the preferred embodiment, such that the term should be limited to the description contained in the discussion of the preferred embodiment.

Here the term "[using] nonstationary signal analysis" must be construed to "continuous wavelet transform" as the patentee has disavowed any construction beyond that disclosed in the preferred embodiment. First, the patent disavows a broader construction by stating that continuous wavelet

transforms are a feature of the invention. The abstract of the patent, states that the patent involves a "method and apparatus for non-invasive, real-time monitoring of the autonomic nervous systems using non-stationary spectral analysis of both heart and respiratory signals. Continuous wavelet transformation is used in real-time so that the dynamic interactions between the sympathetic and parasympathetic divisions of the autonomic nervous system can be independently monitored." In the summary of the invention, the patent does state that the present invention relates to the application of "continuous wavelet transforms," and ordinarily "statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term. Statements that describe the invention as a whole are more likely to be found in certain sections of the specification, such as the Summary of the Invention." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004). Second, the patent disparage other techniques designed to perform non-stationary signal analysis and notes how the technological limitations of these other techniques limits their utility in devices that require real-time frequency and time domain analysis. Accordingly, the Patentee has disavowed any construction of this term beyond that disclosed in the preferred embodiment. Of course, this reading violates the doctrine of claim differentiation; claim 15 of the Patent describes "a method as set forth in claim 1, wherein said non-stationary signal analysis…is continuous wavelet transforms." (Instrument No. 163-2, at 13 ¶ 14:1 -3). Under the Court's reading, there would be no difference between claim 1 and claim 15, because both claim 1 and claim 15 would necessarily employ continuous wavelet transforms to perform non-stationary signal analysis. Nevertheless, the doctrine of claim differentiation is not a hard and fast rule of claim construction, it "only creates a presumption that each claim in a patent has a different scope" and "the written description and prosecution history [may] overcome any presumption arising from the doctrine of claim

differentiation." *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir. 2000); *accord In re Rembrandt Techs, LP*, 496 Fed. Appx. 36, 45 (Fed. Cir. 2012). Here continuous wavelet transforms are the only non-stationary signal analysis contemplated by the patent. Accordingly, the Court adopts the Defendant's proposed construction.

Term No. 3: respiratory activity signals (claim 1)

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
respiratory activity signals	No construction necessary	signals obtained from an impedance pneumography source

a.

The third disputed term is "respiratory activity signals." Plaintiff argues that the meaning of this term is plain and need not be further construed.(Instrument No. 163, at 23). According to Plaintiff, a person of ordinary skill in the art, as well as a lay person, would understand that respiratory activity is simply the process of breathing. Plaintiff further contends that the ordinary meaning comports with the teachings of the specification; the specification teaches that a preferred embodiment of the invention measures the electrical parameters of the lungs as the air volume changes within a patient's lungs. (Instrument No. 163-2, at 8 ¶ 4: 41-50).

Defendant, however, argues that the term "respiratory activity signals" should be construed to mean "signals obtained from an impedance pneumography source." (Instrument No. 165, at 15). Defendant notes that the method of claim 1 requires the determination of an instantaneous respiration frequency (IRF) from a power spectrum created from a "respiratory activity signal." (Instrument No. 163-2, at 12 ¶ 12: 32-36). In turn, the specification teaches how to determine the IRF from a power

spectrum of a signal from an impedance pneumography source (which measures chest movement during breathing). (Instrument No. 163-2, at 8 ¶ 4: 33, 41-42). However, the patent does not teach how to obtain an IRF from the power spectrum of any other signal, thus defendant contends that one of ordinary skill would understand that "respiratory activity signals" is a reference to the impedance pneumography signals in the specification.(Instrument No. 15, at 16).

Plaintiff objects to defendants' construction on the basis that it "takes a single example from the specification and uses it to define the invention." (Instrument No. 166, at 8). Plaintiff admits that the specification does not disclose other methods for gathering "respiratory activity signals," but contends that the patent expressly stated that "methods to gather the [respiratory] data are well known in the art, and thus are not discussed herein in detail." (Instrument No. 163-2, at 8 ¶ 4: 34-36). Thus, it is improper to limit the term "respiratory activity signals" to signals obtained from an impedance pneumography source. (Instrument No. 166, at 8).

b.

The parties' dispute regarding the construction of the term "the surface area of the upper section being a surface area effective to move the upper section upon the creation of a differential pressure thereacross" centers on whether the claim language should be defined in reference to a preferred embodiment. There is no evidence in the intrinsic evidence that the patentee sought to limit the term "respiratory activity signals" to "signals obtained from an impedance pneumography source," as Defendants contend. While it's true that impedance pneumography source is the only apparatus disclosed in the patent that is capable of measuring respiratory signals, it is an elementary principle of claim construction that limitations from a preferred embodiment should not be read into the claim language, unless the patentee evinces a clear intention to limit the scope of the claim language to the

preferred embodiment. *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988). Accordingly, even "when the specification describes a single embodiment to enable the invention, th[e] court will not limit broader claim language to that single application" unless the patentee has demonstrated that the claims themselves, the specification, or the prosecution history "clearly indicate that the invention encompasses no more than that confined structure or method." *Abbott Labs*, 566 F.3d at 1288. As such, respiratory activity signals need not be defined in reference to the apparatuses that measure the signals and should not be defined in reference to the measuring apparatuses unless the patent has disclaimed any broader construction of the term. In this case, there is no evidence of disclaimer. Thus, the Court rejects the defendants' efforts to limit the scope of the claim language by reference to the preferred embodiment.

That said, the definition offered by plaintiff is lacking. The term "respiratory activity signals" could be further defined to provide additional clarity. On review, the Court finds that the term "respiratory activity signals" should be defined to mean "signals indicating a patients breathing activity." This comports with the ordinary and plain meaning of the term, is consistent with the intrinsic record, and provides clarity without unnecessary encumbering the definition.

Term No. 4: "continuous wavelet transform" (claim 21).

Disputed Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**
continuous wavelet transform	A signal processing method for converting time domain signal data into frequency domain signal data by breaking the time domain data into smaller sections and transforming each section using translations and amplifications of a chosen wavelet. Continuous wavelet transform techniques	The agreed mathematical expression below, plus: The continuous wavelet transform possesses the ability to construct a time frequency representation of a signal that offers very good time and frequency localization. $CWT(n, f) = \Delta t \, k(s) \sum_{\mu} x(\mu) \, h * ((n - \mu)/s$

	include the use of computer hardware and software solutions for computing the result of such a transform. Continuous wavelet transforms may be represented generally by the expression $CWT(n, f) = \Delta t\ k(s) \sum_{\mu} x(\mu)\ h\ *\ ((n - \mu)/s \bullet \Delta t)$, *for* $s = f0/f$ whereby: $x(\grave{\imath})$ = a small section of any time-domain data h = any "mother" wavelet Δt is the sampling period; $k(s)$ is a normalizing parameter that depends on the scale factor 's'; * represents complex conjugate; and $f0$ is a constant reference	$\bullet\Delta t)$, *for* $s = f0/f$ whereby: $x(\grave{\imath})$ = a small section of any time-domain data h = any "mother" wavelet Δt is the sampling period; $k(s)$ is a normalizing parameter that depends on the scale factor 's'; * represents complex conjugate; and $f0$ is a constant reference

a.

The fourth disputed term is "continuous wavelet transform." Plaintiff contends that this term should be construed to mean "a signal processing method for converting time domain signal data into frequency domain signal data by breaking the time domain data into smaller sections and transforming each section using translations and amplifications of a chosen wavelet. Continuous wavelet transform techniques include the use of computer hardware and software solutions for computing the result of such a transform. Continuous wavelet transforms may be represented generally by the expression." (Instrument No. 163, at 24-25). According to Plaintiff, a person of ordinary skill in the art would understand continuous wavelet transforms in accordance with the construction suggested by Plaintiff. (Instrument No. 163, at 25).

Defendants, however, contend that the plaintiff's construction is improper because it incorrectly suggests that the continuous wavelet transform only results in a frequency-domain representation signal, when in fact the continuous wavelet transform creates a time-frequency representation of a signal. (Instrument No. 165, at 18). Defendants thus argue that the term "continuous wavelet transform" should be construed to mean the mathematical expression "The agreed mathematical expression below, plus: The continuous wavelet transform possesses the ability to construct a time frequency representation of a signal that offers very good time and frequency localization. $CWT(n, f) = \Delta t\ \mathrm{k}(s) \sum_{\mu} x(\mu)\ h\ ^{*}\ ((n - \mu)/\mathrm{s} \bullet \Delta t)$, *for* $s = f0/f$ whereby: $x(\dot{\imath})$ = a small section of any time-domain data; h = any "mother" wavelet; Δt is the sampling period; $\mathrm{k}(s)$ is a normalizing parameter that depends on the scale factor 's'; * represents complex conjugate; and $f0$ is a constant reference. According to defendants, this definition, particularly the textual explanation accompanying the mathematical expression, is consistent with the specification for the specification teaches that the continuous wavelet transform "provides better time-and frequency resolution of biological signals." (Instrument No. 165, at 17).

Plaintiff contends that Defendants' construction is not supported by the evidence, because the defendants do not provide any support from the intrinsic record for their inclusion of the phrase "very good time and frequency localization" to the description of the continuous wavelet transform. (Instrument No. 166, at 9). According to Plaintiff, the specification's statement that continuous wavelet transform "provides better time and frequency resolution of biological signals" is not specific to continuous wavelet transforms, but is descriptive of all forms of non-stationary spectral analysis. (Instrument No. 166, at 9).

b.

The parties do not dispute the mathematical expression for a continuous wavelet transform; instead the parties' dispute regarding the construction of the term "continuous wavelet transform" hinges on the how that term is understood by a person having ordinary skill the art. In essence, Defendant's construction stresses that continuous wavelet transforms must offer time and frequency localization, while Plaintiff's proposed construction omits this feature. The patent specification teaches that continuous wavelet transform "provides better time-and-frequency resolution of biological signals." (Instrument No. 163-2, at 12 ¶ 11: 54-55). This clearly supports Defendants' reading. That said, the qualitative nature and relativism incumbent in the Defendant's construction—i.e. "a signal that offers very good time and frequency localization"—renders it unsuitable. However, the specification requires that the term be construed with reference to both the time and frequency localization offered by the continuous wavelet transform technique. Accordingly, the Court construes that term" continuous wavelet transform" to mean "a signal processing method for converting time domain signal data into time-domain and frequency-domain signal data by breaking the time domain data into smaller sections and transforming each section using translations and amplifications of a chosen wavelet. Continuous wavelet transform techniques include the use of computer hardware and software solutions for computing the result of such a transform. Continuous wavelet transforms may be represented generally by the expression

$$CWT(n, f) = \Delta t \, \mathrm{k}(s) \sum_{\mu} x(\mu) \, h^{*}((n - \mu)/\mathrm{s} \bullet \Delta t), \, for \, s = f0/f$$

whereby:
$x(i)$ = a small section of any time-domain data
h = any "mother" wavelet
Δt is the sampling period;
k(s) is a normalizing parameter that depends on the scale factor 's';

* represents complex conjugate;
and $f0$ is a constant reference."

Term No. 5: "low frequency area" (claim 2).

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
low frequency area	The energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz, excluding any portion of the selected frequency range that overlaps the frequency range used in calculating the Respiratory Frequency area.	Energy in the power spectrum in the frequency range from 0.04 Hz to 0.1 Hz.

a.

The fifth disputed term is "low frequency area." Plaintiff contends that this term should be construed to mean "the energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz, excluding any portion of the selected frequency range that overlaps the frequency range used in calculating the Respiratory Frequency area." (Instrument No. 163, at 26). According to Plaintiff, this reading is supported by the patent specification because the specification teaches that "frequency-domain standards previously developed, energy in the power spectrum in the frequency range from 0.04 Hz to 0.15 Hz is defined as the low frequency (LF) component, while energy in the frequency range from 0.15 Hz to 0.4 Hz is defined as the high frequency (HF) component." (Instrument No. 163-2, at 11 ¶ 9: 45-47). In Plaintiff's view, the low frequency area is computed using varying ranges of frequencies included in the low frequency range. (Instrument No. 165, at 26).

Defendants claim that the plaintiff's definition is improper because it defines "low frequency area" in terms of "low frequency range," even though the patent treats the two phrases as distinct. (Instrument No. 165, at 18-19). Defendant argues that the patent states that the low frequency range is

0.04 Hz to 0.15 Hz, but the low frequency area is 0.04 Hz to 0.1 Hz. (Instrument No. 165, at 19). Defendant also argues that Plaintiff's suggestion that the low frequency area cannot overlap with the respiratory frequency area is not supported by the specification. (Instrument No. 165, at 19). Defendant thus contends that the phrase "low frequency area" should be construed to mean "energy in the power spectrum in the frequency range from 0.04 Hz to 0.1 Hz." (Instrument No. 165, at 18).

Plaintiff retorts that the Defendants' assertion that because "the specification does not disclose, teach, or enable any other meaning," besides the one they advance ignores an example from the preferred embodiment. Plaintiff insists that the preferred embodiment indicates that the low frequency range of 0.04 HZ to 0.15Hz is the portion of the power spectrum from which the low frequency area can be calculated. (Instrument No. 166, at 10) (citing Instrument No. 163-2, at 11 ¶ 9: 21-25). Plaintiff thus contends that the defendants' construction excludes a preferred embodiment and is therefore is presumptively incorrect. (Instrument No. 166, at 10) (citing *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1138 (Fed. Cir. 2004) ("a claim interpretation that excludes the preferred embodiment is rarely if ever correct")).

b.

The parties' dispute regarding the construction of the term "low frequency area" hinges on whether the "low frequency area" can be defined with reference to the "low frequency range," as the plaintiff proposes or whether the "low frequency area" and the "low frequency range" are two independent metrics, incapable of being used interchangeably, as defendants contend.

Defendants correctly note that the "low frequency area" and "low frequency range" are two different phrases, and thus are presumed to denote two different meanings. However, this does not end the inquiry. The specification teaches that the "low frequency area" is discerned from the heart rate

power spectrum. Specifically, the specification states that "from the frequency domain standards previously developed, energy in the power spectrum in the frequency range from 0.04 Hz to 0.15 Hz is defined as the low frequency (LF) component, while energy in the frequency range from 0.15 to 0.4 Hz is defined as the high frequency (HF) component, LF energy is generally believed to reflect activity in both the sympathetic and parasympathetic systems, while HF energy is generally thought to reflect activity in the parasympathetic system so long as the respiratory frequency remains above 0.15 Hz." (Instrument No. 163-2, at 11 ¶ 9:20-29). However, the specification then continues by noting that in a preferred embodiment "low frequency area is computed as energy in the heart rate power spectrum between 0.04 Hz and 0.1 Hz.[;] this measurement is indicative of the activity in the sympathetic system." (Instrument No. 163-2, at 11 ¶ 9:42-48).

While it is true that the preferred embodiment suggests an LFa with a range of only 0.04 Hz to 0.1 Hz, that does not mean that the scope of the claim language is limited to the description of the preferred embodiment. That said, nothing about plaintiff's reading seems inherent: there is no reason, from the face of the patent or the specification, that the low frequency area must be defined to exclude any frequency range that is used in calculating the RFa. The specification merely teaches that the LFa is discerned from energy in the heart power spectrum in the "frequency range from 0.04 HZ to 0.15 Hz. (Instrument No. 163-2, at 11 ¶ 9:20 -22). Accordingly, the Court construes the term "low frequency area" to mean "the energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz."

Term No. 6: "respiration frequency area" (claim 2).

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
respiration frequency area	Energy in the heart rate power spectrum in a range of frequencies containing the respiration peak frequency that is scaled to the value of the respiration peak frequency	Energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration

a.

The sixth disputed term is "respiration frequency area." Plaintiff contends that this term should be construed to mean "energy in the heart rate power spectrum in a range of frequencies containing the respiration peak frequency that is scaled to the value of the respiration peak frequency." (Instrument No. 165, at 28). According to Plaintiff, this construction flows from the claim language: claim 2 clearly provides that "respiration frequency area" is computed from a second power spectrum, identified in claim 1 as a power spectrum computed from the respiratory activity signals. (Instrument No. 163-2, at 12 ¶ 12: 44-43; 33-34). Plaintiff further contends that this definition also comports with the specification which teaches that "the respiratory frequency area (RFa) is computed as the energy in the heart rate power spectrum under the respiration peak frequency... This measurement is indicative of the activity in the parasympathetic system." (Instrument No. 165, at 28) (quoting Instrument No. 163-2, at 11 ¶ 9: 48 - 55)).

Defendants contend that Plaintiff's construction, though similar to defendants' proposed construction, does not find direct support in the intrinsic record; the wording of plaintiff's construction does not directly descend from the intrinsic record. Defendant thus asks that the term "respiration frequency area" be defined to mean "energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration." (Instrument No. 165, at 19). Defendants claim that this definition is supported by the patent

specification, which teaches that "The respiratory frequency area (RFa) is computed as the energy in the heart rate power spectrum under the respiration peak frequency (IRF), calculated using a window whose bandwidth is proportional to the frequency of respiration." (Instrument No. 163-2, at 11 ¶ 9: 48 -52).

In the Reply, Plaintiff argues that the defendants' definition improperly imports a limitation from a preferred embodiment to narrow the scope of the disputed term. (Instrument No. 166, at 10). According to Plaintiff, defendants' construction adds the limitation that the proportionality of the respiration peak frequency to the respiration frequency area be implemented through a windowing function, while plaintiff's definition merely requires a proportional relationship between the respiration peak frequency and respiration frequency area. (Instrument No. 166, at 10-11).

b.

The difference between the parties' definitions is minor; both parties recognize that their proposed constructions are substantively similar. *See* (Instrument No. 165, at 20); (Instrument No. 163, at 29). Plaintiff argues that the defendants' construction imports a limitation from the preferred embodiment into the claim language. However, the specification offers clear support for the defendants' construction; the specification states that in a preferred embodiment "the respiratory frequency area (RFa) is computed as the energy in the heart rate power spectrum under the respiratory peak frequency, (IRF), calculated using a window whose bandwidth is proportional to the frequency of respiration." (Instrument No. 163-2, at 11 ¶ 9: 48-52). Plaintiff cites to this portion of the specification as evidence that there must be a proportional relationship between the respiration frequency peak and the respiration frequency area; defendant, however, uses this same portion of the specification as evidence that the proportional relationship between the respiration frequency peak and the respiration frequency area must be achieved using a windowing function. On balance, the Court finds that the defendants' construction

though taken verbatim from the specification does add an unnecessary limitation. Although it is true that the patent does not disclose any other method for transforming the respiration frequency peak to the respiration frequency area, the essence of specification, only requires proportionality between the respiration frequency peak and the respiration frequency area, the method by which this proportionality is achieved is not essential to the invention. Accordingly, the Court finds that the term "respiration frequency area" should be construed to mean "energy in the heart rate power spectrum under the respiration peak frequency calculated using a range of frequencies whose bandwidth is proportional to the frequency of respiration." This definition comports with the patent specification without adding unnecessary limitations.

Term No. 7: "level of sympathovagal balance" (claim 2).

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
level of sympathovagal balance	a level of the balance of the sympathetic system and the parasympathetic system	The ratio LFa/RFa.

a.

The seventh disputed term is "a level of sympathovagal balance." Plaintiff contends that this term should be construed to mean "a level of the balance of the sympathetic system and the parasympathetic system." (Instrument No. 163, at 29). Plaintiff argues that its proposed construction is consistent with teachings of the patent specification. According to Plaintiff, specification defines the term "sympathovagal balance" as the "balance between the sympathetic system and the parasympathetic system." (Instrument No. 163-2, at 11, ¶ 10: 34-36). Plaintiff thus contends that the Court should adopt its construction.

Defendants, however, contend that the term "a level of sympathovagal balance" should be defined to mean "the ratio of LFa/RFa," because the specification teaches that the ratio LFa/ RFa is "indicative of sympathovagal balance," *see* (Instrument No. 163-2, at 11, ¶ 9: 55-57), and does not disclose any other means by which to measure the sympathovagal balance from a power spectrum. Accordingly, defendants contend that the term should be limited to the method disclosed in the patent specification. (Instrument No. 165, at 21).

Plaintiff once again argues that defendants are seeking to improperly confine the definition of a claim term to the disclosed embodiments. (Instrument No. 166, at 11). The plaintiff, thus, asks this Court to reject the defendants' reading. (Instrument No. 166, at 11).

b.

The dispute between the parties' proposed constructions centers on whether the term "a level of sympathovagal balance" should be limited to the method disclosed in the preferred embodiment, as defendants propose, or whether it should be defined more generally without reference to the method disclosed in the preferred embodiment, as plaintiff proposes. On review, the Court adopts the plaintiff's proposed construction. The defendants' construction unnecessarily imports a limitation from the preferred embodiment. Although the preferred embodiment uses the ratio LFa/ RFa to approximate the level of "sympathovagal balance" the patent specification clearly defines the term "sympathovagal balance" as the "balance between the sympathetic system and the parasympathetic system." (Instrument No. 163-2, at 11, ¶ 10: 34-36). Thus, the LFa/ RFa is one measure of sympathovagal balance; it is not, in and of itself, the definition of sympathovagal balance. Accordingly, defendants' construction is too narrow. Plaintiff's construction adheres to the specification without importing an unnecessary limitation

from the specification. Therefore, the Court construes the term "level of sympathovagal balance" to mean "a level of the balance of the sympathetic system and the parasympathetic system."

Term No. 8: "a level of sympathetic activity" and a "level of parasympathetic activity" (claim 2).

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
a level of sympathetic activity	construed under claim 1; no construction necessary	energy in the heart rate power spectrum between 0.04 and 0.1 Hz
a level of parasympathetic activity	construed under claim 1; no construction necessary	energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration

a.

The eighth disputed term is "a level of sympathetic activity" and a "level of parasympathetic activity." Plaintiff contends that this term was construed in disputed term one— determining] a level of sympathetic and parasympathetic activity—and the term should be construed the same way here. (Instrument No. 163, at 30). The defendants, however, contend that the phrase "a level of sympathetic activity" should be construed to mean "energy in the heart rate power spectrum between 0.04 and 0.1 Hz" and the phrase "a level of parasympathetic activity" should be defined as "energy in the heart rate power spectrum under the respiration peak frequency calculated using a window whose bandwidth is proportional to the frequency of respiration." (Instrument No. 165, at 21). Defendants, like plaintiff, urge that these terms be defined in accordance with the parties' proposed definition for term one. (Instrument No. 165, at 21).

b.

The eight disputed term "a level of sympathetic activity" and a "level of parasympathetic activity" is housed in claim 2 of the patent. Claim 2 depends from claim 1, thus it uses the terms "a level

of sympathetic activity" and a "level of parasympathetic activity" in the same manner as these terms were used in claim 1. Accordingly, the construction of "a level of sympathetic activity" and a "level of parasympathetic activity" under claim one should also be applied to claim 2. The claim 1 terms were construed in connection with first disputed term. As such, the Court finds that these terms have been defined under claim 1 and do not require further construction.

Term No. 9: "coupled" (claim 2).

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
coupled	No construction necessary Alternative construction: "linked, accompanied, or associated"	Linked

a.

The ninth disputed term is "coupled." Plaintiff contends that the definition is readily understood by a lay person and one skilled in the art and therefore does not require further construction. (Instrument No. 163, at 31). Defendants, however, contend that the term "coupled" is ambiguous and can mean different things in different contexts; defendants, thus, argue that the term should be further defined. Specifically, the defendants propose that the term "coupled" be defined to mean "linked." (Instrument No. 165, at 21). According to defendants, this definition is in keeping with the plain and ordinary meaning of the term and avoids the confusion of plaintiff's construction. (Instrument No. 165, at 22). In reply, Plaintiff maintains that the term "coupled" need not be construed, but if further construction is required then the plaintiff asks that the term be defined to mean "linked, accompanied, or associated." (Instrument No. 166, at 12).

b.

The definition of the word "coupled" is plain and is readily understood by both layman and a person skilled in the art. Accordingly, it is not obvious why the term would require further construction. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.,* 521 F.3d 1351, 1360 (Fed. Cir. 2008) (noting that when the definition of a term is plain, it need not be further construed). However, to the extent that the term coupled could be ambiguous, the plaintiff's alternative construction of "linked, accompanied, or associated" seems to clarify the ambiguity, while defining the term in accordance with its plain and ordinary meaning. Accordingly, the Court defines the term "coupled" to mean "linked, accompanied, or associated."

B.

Term No. 1: "modified Bartlett window " (claim 1)

Disputed Term	**Plaintiff's Proposed Construction**	**Defendants' Proposed Construction**
modified Bartlett window	A mathematical function that may be represented by a modified triangle and is useful for windowing, selecting a range of a signal for analysis, while emphasizing certain data within that range and minimizing other data within the range	A window as shown in Figure 6, 7, or 8 of the '579 patent

a.

The first disputed term of the '579 patent is "modified Bartlett window." Plaintiff claims that this term should be construed to mean "a mathematical function that may be represented by a modified triangle and is useful for windowing, selecting a range of a signal for analysis, while emphasizing certain data within that range and minimizing other data within the range." (Instrument No. 163, at 33). According to Plaintiff, this definition best adheres to the patent specification which teaches that a normal Bartlett window is a mathematical function represented by a triangle, wherein the window has a zero value outside the analysis window with a linear increase to 1 occurring at the midpoint of the window and a linear decrease back to 0 at the end of the window. '579 Patent at 4:7-10. The specification further teaches that the "modified Bartlett window" is a form of an analysis window which is multiplied with the source waveform to result in a product that is deemphasized for a certain period and emphasized for another period. The '579 Patent at 5:51–6:3. Accordingly, Plaintiff argues that its construction comports with the specification.

Defendants argue that Plaintiff's definition in unsatisfactory because the term "modified" can encompass almost any "modification" to the Bartlett window. According to defendants, this is improper because the patent contemplates a triangular window, yet the word "modified," as defined by Plaintiffs could also accommodate a rectangular window. (Instrument No. 165, at 23). Defendants, thus, contend that the term "modified Bartlett window" should be defined to mean "any of the windows shown in Figures 6, 7, and 8 of the patent." (Instrument No. 165, at 22). Defendants argue that this definition is anchored in the specification because the only examples of a modified Bartlett window included in the specification are the: (1) an inverted or "notched" window, described in Figure 6; (2) the negative slope window, depicted in Figure 7; and (3) a positive slope window, depicted in Figure 8. '579 patent (col.6, l.60 to col.7, l.7); '579 patent (col.3, ll.39-51). Thus, Defendants argue that its definition best comports with the patent specification.

According to Plaintiff, the defendants' construction is objectionable because it attempts limit the claim scope to the description of a preferred embodiment, in contravention of elementary claim construction of precepts. (Instrument No. 166, at 13).

b.

The "modified Bartlett window" is a form of an analysis, where a triangle used for windowing is multiplied with the source waveform to result in a product that is deemphasized for a certain period and emphasized for another period. The '579 Patent at 5:51–6:3. The '579 Patent shows a normal Bartlett window at Figure 14, reproduced below, wherein the window has a zero value outside the analysis window with a linear increase to 1 occurring at the midpoint of the window and a linear decrease back to 0 at the end of the window. '579 Patent at 4:7-10. The specification discusses a modified Bartlett windows" in discussing a preferred embodiment, which uses an analysis window, referred to as an

"inverse Bartlett window", Figure 11 below, with a wave form that is 0 for all time values up to the beginning of the window, instantaneously becomes 1 at the beginning of the window, then linearly decreases from 1 to 0 by the midpoint of the window and linearly increases from 0 to 1 by the end of the window. '579 Patent at 5:51-60. At the very end of the window, the analysis window's wave form transitions abruptly from 1 to 0 through all values in the future. Id. Figure 11 of the '579 Patent, below, provides an example of a "modified Bartlett window", and demonstrates the 0 valued multiplier for data outside the analysis window and instantaneous transition to 1 and linear decease to 0 until the midpoint of the analysis window then the linear increase back to 1 until the end of the analysis window with an abrupt transition back to 0 for the remainder of the future values outside the window. This inverse window, though, is just one possible modification of a traditional Bartlett window, it, along with the other examples included in the specification to do not define the entire universe of such modifications. Accordingly, the Court finds that the defendants' construction unnecessarily and impermissible seeks to limit the scope of the claim language to the disclosed methods in a preferred embodiment. *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1314 (Fed. Cir. 2008) (finding a "description of a preferred embodiment, in the absence of a clear intention to limit claim scope, is an insufficient basis ... to narrow the claims"). Accordingly, the Court rejects the defendants' construction. However, the Court finds that the plaintiff's construction defines the term "modified Bartlett window" consistent with the patent specification without being overly restrictive or encumbering. Accordingly, the Court adopts the plaintiff's proposed definition.

Term No. 2: "low frequency area" (claim 1)

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
low frequency area	The energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz, excluding any portion of the selected frequency range that overlaps the frequency range used in calculating the Respiratory Frequency area	Energy in the power spectrum in the frequency range from 0.04 Hz to 0.1 Hz.

a.

The second disputed term of the '579 Patent is "low frequency area." Plaintiff and Defendant both contend that this term should be construed in a manner consistent with the construction of "low frequency area" in the '888 patent. Specifically, Plaintiff contends that the disputed term "low frequency area" should be defined to mean "the energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz, excluding any portion of the selected frequency range that overlaps the frequency range used in calculating the Respiratory Frequency area." (Instrument No. 163, at 35). According to Plaintiff, this definition is proper because the specification directly compares low frequency areas computed according to the method of the '579 Patent with low frequency areas computed from the same data according to the method of the '888 Patent; thus the term should be defined consistently in both the '579 patent and the '888 patent. Plaintiff further states that a person of ordinary skill in the art would also know that the term "low frequency area," as used in the '579 patent references a low frequency (LF) value as the area under the curve in the low frequency range of the heart rate power spectrum. Thus, Plaintiff contends its definition is proper. Defendant, contends, that the plaintiff's construction improperly conflates "low frequency range" with "low frequency area". In defendants' view, these two phrases have distinct meanings and cannot be interchanged. Accordingly,

the defendants asks that the term "low frequency area" be construed to mean "energy in the power spectrum in the frequency range from 0.04 Hz to 0.1 Hz." (Instrument No. 165, at 24).

b.

As Plaintiff aptly noted the specification directly compares low frequency areas computed according to the method of the '579 Patent with low frequency areas computed from the same data according to the method of the '888 Patent. This is a strong indication that the term "low frequency area" should be defined consistently in both the '579 patent and the '888 patent. Because the Court defined "low frequency area" in the '888 patent to mean "the energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz," the Court will also define "low frequency area" in the '579 patent to mean "the energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz."

V.

For the reasons stated above, the Court hereby adopts the following definitions for each of the disputed claim terms as follows:

Disputed Terms of the '888 Patent

#	Patent & Claim	Disputed Term	Court's Construction
1	'888, clm. 1	[determining] a level of sympathetic and parasympathetic activity	A value for the sympathetic nervous system reflecting its activity and a value for the parasympathetic nervous system reflecting its activity.
2	'888, clm. 1	[using] nonstationary signal analysis	Continuous wavelet transform
3	'888, clm. 1	respiratory activity signals	"Signals indicating a patients breathing activity."
4	'888, clm. 21	continuous wavelet transform	A signal processing method for converting time domain signal data into time-domain and frequency-domain signal data by breaking the time domain data into smaller sections and transforming each section using translations and amplifications of a chosen wavelet. Continuous wavelet transform techniques include the use of computer hardware and software solutions for computing the result of such a transform. Continuous wavelet transforms may be represented generally by the expression $CWT(n,f) = \Delta t\ \mathrm{k}(s) \sum_{\mu} x(\mu)\ h\ *\ ((n - \mu)/\mathrm{s} \bullet \Delta t), for\ s = f0/f$ whereby: $x(i)$ = a small section of any time-domain data h = any "mother" wavelet Δt is the sampling period; k(s) is a normalizing parameter that depends on the scale factor 's'; * represents complex conjugate; and

			*f*0 is a constant reference
5	'888, clm. 2	low frequency area	The energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz.
6	'888, clm. 2	respiration frequency area	Energy in the heart rate power spectrum under the respiration peak frequency calculated using a range of frequencies whose bandwidth is proportional to the frequency of respiration.
7	'888, clm. 2	a level of sympathovagal balance	A level of the balance of the sympathetic system and the parasympathetic system
8	'888, clm. 2	a level of sympathetic activity	construed under claim 1; no construction necessary
		a level of parasympathetic activity	construed under claim 1, no construction necessary
9	'888, clm. 2	coupled	Linked, accompanied, or associated

Disputed Terms of the '579 Patent

#	Patent & Claim	Disputed Term	Court's Construction
1	'579, clm. 1	modified Bartlett window	A mathematical function that may be represented by a modified triangle and is useful for windowing, selecting a range of a signal for analysis, while emphasizing certain data within that range and minimizing other data within the range
2	'579, clm. 1	low frequency area	The energy in the heart rate power spectrum in a selected frequency range between .04 hertz and 0.15 hertz.

The Clerk shall enter this Order and provide a copy to all parties.

SIGNED on this the 30th day of August, 2013, at Houston, Texas.

VANESSA D. GILMORE
UNITED STATES DISTRICT JUDGE